From: <joy_evered@mail.fws.gov>, on 1/19/98 1:20 PM:
To: George Mitchell@OD@FDACVM

Docket No. 97N-0217

Comments on the Discussion Draft: "Proposals to increase the availability of approved animal drugs for minor species and minor uses"

January 19, 1998

To: Dr. Bert Mitchell
Center for Veterinary Medicine (HFV-6)
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Dear Dr. Mitchell,

I very much support the concepts explained in the Draft Discussion that CVM will consider Non-food life stages of food producing animals. This is especially significant for the Resource Enhancement Branch of the Aquaculture Industry in which species such as Pacific salmon are reared for only a few months and then released and do not return to be caught for more than a year.

Comments on section IV A. Modification of Extralabel Provisions-
I support the modification that will allow the use of approved medicated feeds and reproductive hormones for minor species as extralabel dosage form products. The "Sunset period" mentioned in the Draft is ten years, but, a time of five to seven years may be more of an incentive to get the required work started immediately, instead of putting it off for a few years.

Comments on section IV F. 1) Creation by Statute of Minor Use Animal Drugs-
I support the designation of a "minor use animal drug" category that is based on the established "human orphan drug" program already being used. The Aquaculture industry has already experienced many drug availability problems due to the small market it provides to drug companies.

Comments on section IV G. Conditional Drug Approval for Minor Uses Involving Non-Food Animals-
I support a Conditional Drug Approval Category for minor uses involving non-food animals and non-food life stages of food animals. However, in the Aquaculture Industry, we are able to rapidly generate the treatment efficacy data but are much slower at generating the human food safety, environmental fate, and target animal safety data. For many of the compounds being considered for approval by the aquaculture community, the data exists for everything but efficacy and target animal safety. Therefore, a conditional approval of these compounds would allow us to concentrate our resources to provide the necessary data efficiently and without generating large

amounts of extraneous information that may bog down the approval process. With the designation of non-food life stages of food animals that provide withdrawal times of several months to years, this category of approvals will still provide sufficient consumer protection.

Thank you for your consideration of my comments on these ADAA Discussion Draft issues.

Sincerely,

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